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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

18N2/1223

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER,
1300 I STREET, NW,
WASHINGTON DC 20005-3315

ART UNIT	PAPER NUMBER
DRAPER, G	12

DATE MAILED: 12/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11-18-96; 4-29-97, 5-14-97, and 8-13-97.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 24, 27-39, 49-53, 67-106 is/are pending in the application.

Of the above, claim(s) 27-39 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 24, 49-53, 67-106 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10 of [illegible] 8-8-97

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

1. The following claims are pending of record. Claims: 24,27-30,31-39,49-53,67-68, and 69-106.

2. Newly submitted claims 27-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims constitute a patentably distinct inventive concept and are related to the original claims (19-21 and 24) as "Product and process of use". In the instant case the various polypeptides can be used to make Antibodies, used as a probe or used in various distinct therapeutic or diagnostic methods. Further, there are different issues for the search an examination of each, and to examine these claims in addition to the other inventive concept that was elected by original presentation would pose a burden on the examine.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It is further pointed out that the first action on the merits issued on 11-14-96 and the Pre-Amendment, with the proposed addition of claims 27-30 has a filing date of 11-18-96 which is not before the issuance of the first office action and is, therefore, not a proper Preliminary Amendment. Claims 31-39 were added by the Amendment dated 4-29-97 which is clearly considerably after the first office action. It is also pointed out that prior to applicants filing of the amendment of 11-18-96, applicants were aware of the fact that actions on the merits were being issue in this and related files because of a telephone conversation with the examiner, but applicants failed to inform the Examiner that any Pre-Amendment would be filed, nor was the Paper hand-carried or faxed as a means to expedite the Paper/Amendment. Based on **all** of the above, these claims should be canceled.

3. This office action is directed to the merits of claims 24,49-53,67-68 and 69-106.

4. Since the first office action, applicants have submitted 4 amendment/supplemental amendments that have been either incomplete or piecemeal. The last amendment refers to arguments in the previous amendment. Applicants representative have done this in all six of these related files. Applicant should refrain from such and should attempt to submit a complete a thorough amendment in single form in all subsequent amendments (see MPEP 714). It is further pointed out that in view of the extensive nature of the amendment and the number of added claims, applicants should file proper amendments which clearly state where, in the specification, support/enablement lies for these numerous amendments.

5. Claims 24,49-53,67-68,69-106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mature and precursor form of the TNF receptor and for certain mutations, does not reasonably provide enablement for a) compositions of any functional derivatives or fragments as in claim 24; b) the addition of any one of the 20 amino acids at the N and/or C-terminal of the protein (claims 49-53) or any length that shortens the N and/or C-terminal (claims 69-106,67-68). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make an and use the invention commensurate in scope with these claims. There are insufficient examples and guidance to enable the skilled artisan to practice the full scope of the claims. The nature, make-up and extent of the derivative and fragments have not been taught. Applicants have not provided structure/function studies, or regions that are important for either the structure and/or function of the product, thus, in the absence of sufficient examples this does not provide enablement for the skilled artisan to make and use the full scope of these modifications with a reasonable assurance that these products will possess the desired activity. How long should the fragment be, what activity should it possess, and does it have to cover a structural or functional region? The mere recitation of "boiler plate templates" for how one modifies a product or test for its activity, on its face is not sufficient guidance. Absent sufficient example, the specification should direct the artisan to certain regions where the product can or can not tolerate changes, and also provide

some guidance for the nature of these changes. In the absence of such, the skilled artisan would be faced with undue experimentation.

Claim 24 is non-enabling for the elements specified above and for the reasons set forth in the previous office action.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 24, 49-53, 67-68 and 69-106 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallach et al.

The prior art discloses a protein that is the same as that disclosed despite the fact that the protein is referred to by a different name, and the instant claims recite additional characteristics of the protein. Based on all of the identifying characteristic the prior art protein anticipate the claims, and any properties recited by the instant claims that are not recited in the prior art merely represent further characterization of the protein, wherein such properties are inherent to the protein (In re Swinehart, 169 USPQ 226). Although the claims, in some instances, recite amino acid or nucleic acid sequence information, it is well known that the amino acid sequence is inherent to the protein, and based on the partial sequence provided by the prior art, the skilled artisan would have reasonably expected that the protein are the same. With regard to the nucleic acid sequence, it is also known that because of codon degeneracy, different nucleic acid sequence can encode for the same protein, but these different nucleic acids do not make the resulting protein per se different. Therefore, the burden is therefore upon applicants to established a patentable difference (In re Best 195 USPQ 430).

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Draper, G.D. whose telephone number is (703) 308-4232.

Art Unit: 1812

Draper/sg
November 14, 1997
December 23, 1997

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800